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EXAMINER	
HURST, JONATHAN M	

ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/551,148	OGIWARA ET AL.	
	Examiner	Art Unit	
	JONATHAN M. HURST	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/29/2005, 01/20/2006, and 02/13/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-11 are not commensurate in scope with the preamble because it is unclear where an analysis step takes place and as such it is unclear whether the claims are directed to an analyzing method or a method of data manipulation.

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1-22 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Regarding claims 1-11, claims 1-11 are directed the mental steps of correcting and comparing data and as such do not represent statutory subject matter.

Regarding claims 12-22, claims 12-22 are directed to a computer program and are not claimed as embodied in a computer readable medium and computer programs claimed as computer listings *per se*, i.e., the descriptions or expressions of the programs, are not physical "things." They are neither computer components nor statutory processes, as they are not "acts" being performed. Such claimed computer programs do not define any structural and functional interrelationships between the computer program and other claimed elements of a computer which permit the computer program's functionality to be realized. In contrast, a claimed computer-readable medium encoded with a computer program is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program's functionality to be realized, and is thus statutory. See *Lowry*, 32 F.3d at 1583-84, 32 USPQ2d at 1035. Accordingly, it is important to distinguish claims that define descriptive material *per se* from claims that define statutory inventions. (See MPEP 2106.01)

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-9, 11, 14-20, and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Norton (US 6,989,100).

Regarding claim 1 Norton discloses a sample analyzing method, which comprises:

a step (a) of correcting at least a one-dimensional parameter in multi-dimensional data obtained as a result of the analysis of a sample; and

a step (b) of comparing the corrected data obtained in said step (a) for multiple samples.

(See Col. 1 Lines 15-21 and Col. 1 Lines 40-43 where in samples comprising multidimensional data retention time is corrected through time-aligning and the corrected data is compared among samples)

Regarding claim 2 Norton discloses all the claim limitations as set forth above as well as the sample analyzing method wherein said multi-dimensional data is three-dimensional data consisting of a parameter indicating a mass-to-charge ratio, a

parameter indicating ionic intensity, and a parameter indicating a retention time, obtained as a result of chromatography mass spectrometry, and wherein the parameter indicating a retention time is corrected in said step (a).

(See Col. 1 Lines 15-21 where the parameters are disclosed and Col. 1 Lines 40-43 where retention time is corrected through time-aligning)

Regarding claim 3 Norton discloses all the claim limitations as set forth above as well as the sample analyzing method wherein, in said step (a), profiles regarding parameters, from which a parameter as a correction target has been excluded, are used as reference profiles, and wherein using an evaluation function acting as a scale of position similarity regarding a plurality of reference profiles among multiple samples, the position of each profile is determined as a problem of finding an optimum solution which optimizes the value of said evaluation function.
(See Col. 6 Lines 17-53 where profiles are data sets and data sets not being corrected are reference data sets and multiple sample data sets are compared to reference data sets based on similarity using a function and an optimum solution is found based on said function)

Regarding claim 4 Norton discloses all the claim limitations as set forth above as well as the sample analyzing method wherein said evaluation function is

defined with one or more terms selected from the group consisting of the following terms (1) to (5):

(1) a term regarding similarity and/or distance among profiles regarding a parameter of a correction target;

(See Col. 6 Lines 30-53 where the function (2) contains a term regarding the distance among data sets)

Regarding claim 5 Norton discloses all the claim limitations as set forth above as well as the sample analyzing method wherein, in said step (a), dynamic programming algorithm is used, when the value of said evaluation function is optimized as a problem of finding an optimum solution regarding said parameter of a correction target.
(See Col. 6 Lines 53-60 where a dynamic program is used to find an optimum solution to a function to correct a parameter of a target sample)

Regarding claim 6 Norton discloses all the claim limitations as set forth above as well as the sample analyzing method wherein, in said dynamic programming algorithm, when the optimal correspondence of data points contained in a parameter of a correction target is evaluated by calculating scores, the score of a correspondence regarding data points derived from a reference material is set by a point-addition scoring system.

(See Col 6 Lines 17-60 where a dynamic program is used to find an optimal solution to function (2) by using a score, which is a distance, calculated by adding terms)

Regarding claim 7 Norton discloses all the claim limitations as set forth above as well as the sample analyzing method wherein, in said dynamic programming algorithm, when the optimal correspondence of data points contained in a parameter of a correction target is evaluated by calculating scores, a constraint condition is set, in which a correspondence regarding data points derived from a reference material is necessarily corresponded at a designated point.
(See Col. 8 Lines 16-33 where a constraint regarding data analyzed is set so the data must correspond to each other in at least one point or peak.)

Regarding claim 8 Norton discloses all the claim limitations as set forth above as well as the sample analyzing method wherein said sample comprises a protein group and/or a peptide group. (See Example 1 where human serum comprises proteins)

Regarding claim 9 Norton discloses all the claim limitations as set forth above as well as the sample analyzing method wherein said multiple samples comprise a reference material. (See Col. 4 Lines 35-50 where a reference material is selected from among samples)

Regarding claim 11 Norton discloses all the claim limitations as set forth above as well as the sample analyzing method wherein said reference material is added to said sample in a state where it is immobilized in gel. (See Col. 3 Lines 50-55 where sample is added in gel form and Col. 4 Lines 36-50 where reference material is a sample)

Regarding claim 12 Norton discloses a sample analyzing program for allowing a computer to execute:

> a procedure (a) of inputting multi-dimensional data obtained as a result of the analysis of a sample;
>
> a procedure (b) of correcting the data of at least a one-dimensional parameter from among the inputted multi-dimensional data; and
>
> a procedure (c) of comparing multi-dimensional data including the data corrected in said procedure (b) for multiple samples.

(See Col. 4 Lines 4-10 where data is input into a computer as a result of the use of an analytical instrument Col. 1 Lines 15-21 and Col. 1 Lines 40-43 where retention time is corrected through time-aligning and corrected data is compared among samples)

Regarding claim 13 Norton discloses all the claim limitations as set forth above as well as the sample analyzing program wherein said multi dimensional data is three-dimensional data consisting of a parameter indicating a mass to-charge ratio, a parameter indicating ionic intensity, and a parameter indicating a retention time, obtained as a result of chromatography mass spectrometry, and wherein the parameter indicating a retention time is corrected in said procedure (b).
(See Col. 1 Lines 15-21 where parameters are disclosed and Col. 1 Lines 40-43 where retention time is corrected through time-aligning)

Regarding claim 14 Norton discloses all the claim limitations as set forth above as well as the sample analyzing program wherein wherein, in said procedure (b), profiles regarding parameters, from which a parameter as a correction target has been excluded, are used as reference profiles, and wherein using an evaluation function acting as a scale of position similarity regarding a plurality of reference profiles among multiple samples, the position of each profile is determined by optimizing the value of said evaluation function as a problem of finding an optimum solution.
(See Col. 6 Lines 17-53 where profiles are data sets and data sets not being corrected are reference data sets and multiple sample data sets are compared to reference data sets based on similarity using a function and an optimum solution is found based on said function)

Regarding claim 15 Norton discloses all the claim limitations as set forth above as well as the sample analyzing program wherein said evaluation function is defined with one or more terms

(1) a term regarding similarity and/or distance among profiles regarding a parameter of a correction target;

(See Col. 6 Lines 30-53 where the function (2) contains a term regarding the distance among data sets)

Regarding claim 16 Norton discloses all the claim limitations as set forth above as well as the sample analyzing program wherein, in said procedure (a), dynamic programming algorithm is used, when the value of said evaluation function is optimized as a problem of finding an optimum solution regarding said parameter of a correction target.
(See Col. 6 Lines 53-60 where a dynamic program is used to find an optimum solution to a function to correct a parameter of a target sample)

Regarding claim 17 Norton discloses all the claim limitations as set forth above as well as the sample analyzing program wherein, in said dynamic programming algorithm, when the optimal correspondence of data points contained in a parameter of a correction target is evaluated by calculating scores, the score of a correspondence

regarding data points derived from a reference material is set by a point-addition scoring system.

(See Col 6 Lines 17-60 where a dynamic program is used to find an optimal solution to function (2) by using a score, which is a distance, calculated by adding terms)

Regarding claim 18 Norton discloses all the claim limitations as set forth above as well as the sample analyzing program wherein in said dynamic programming algorithm, when the optimal correspondence of data points contained in a parameter of a correction target is evaluated by calculating scores, a constraint condition is set, in which a correspondence regarding data points derived from a reference material is necessarily corresponded at a designated point.

(See Col. 8 Lines 16-33 where a constraint regarding data analyzed is set so the data must correspond to each other in at least one point or peak.)

Regarding claim 19 Norton discloses all the claim limitations as set forth above as well as the he sample analyzing program wherein said sample comprises a protein group and/or a peptide group, and wherein multi-dimensional data derived from said protein group and/or peptide group are analyzed. (See Example 1 where a sample comprises human serum which comprises proteins and data is obtained from said sample and analyzed)

Regarding claim 20 Norton discloses all the claim limitations as set forth above as well as the he sample analyzing program wherein said multiple samples comprise reference materials, and wherein multi-dimensional data derived from these reference materials and multi-dimensional data derived from components contained in said samples are used in said procedure (b). (See Col. 4 Lines 35-50 where a reference material is selected from among samples and data is aligned)

Regarding claim 22 Norton discloses all the claim limitations as set forth above as well as the sample analyzing program wherein said reference material is added to said sample in a state where it is immobilized in gel. (See Col. 3 Lines 50-55 where sample is added in gel form and Col. 4 Lines 36-50 where reference material is a sample)

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 10 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norton (US 6,989,100) as applied to claims 1-9, 11, 14-20, and 22 above, and further in view of Teschemacher et al. (US 4,681,871)

Regarding claim 10 Norton discloses all the claim limitations as set forth above but does not specifically disclose the sample analyzing method wherein said reference material is at least one type of peptide selected from the group consisting of peptide T (Ala-Ser Thr-Thr-Asn-Tyr-Thr), beta-casomorphin-7 (Tyr-Pro-Phe-Pro-Gly-Pro-Ile), and a structural analog thereof.

Teschemacher et al. discloses a sample analyzing method wherein a sample is analyzed based on the use of liquid chromatography and wherein the sample contains beta-casomorphin-7 (Tyr-Pro-Phe-Pro-Gly-Pro-Ile). (See Example 1 where beta-casomorphin-7 is isolated as a result of liquid chromatography)

It would have been obvious to one of ordinary skill in the art at the time of invention to use beta-casomorphin-7 (Tyr-Pro-Phe-Pro-Gly-Pro-Ile) as disclosed by Teschemacher as the reference material in the sample analyzing method of Norton because beta-casomorphin-7 fulfills the need for a specific biological sample to be

analyzed which is compatible with chromatographic instruments and can be used as a reference material (See Norton Col. 3 Lines 50-66 and Col. 4 Lines 36-50) and is known to be analyzed using chromatographic methods.

Regarding claim 21 Norton discloses all the claim limitations as set forth above but does not specifically disclose the sample analyzing program wherein said reference material is at least one type of peptide selected from the group consisting of peptide T (Ala-Ser-Thr-Thr-Asn-Tyr-Thr), beta-casomorphin-7 (Tyr-Pro-Phe-Pro-Gly-Pro-Ile), and a structural analog thereof.

Teschemacher et al. discloses a sample analyzing method wherein a sample is analyzed based on the use of liquid chromatography and wherein the sample contains beta-casomorphin-7 (Tyr-Pro-Phe-Pro-Gly-Pro-Ile). (See Example 1 where beta-casomorphin-7 is isolated as a result of liquid chromatography)

It would have been obvious to one of ordinary skill in the art at the time of invention to use beta-casomorphin-7 (Tyr-Pro-Phe-Pro-Gly-Pro-Ile) as disclosed by Teschemacher as the reference material in the sample analyzing program of Norton because beta-casomorphin-7 fulfills the need for a specific biological sample to be analyzed which is compatible with chromatographic instruments and can be used as a reference material (See Norton Col. 3 Lines 50-66 and Col. 4 Lines 36-50) and is known to be analyzed using chromatographic methods.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN M. HURST whose telephone number is (571)270-7065. The examiner can normally be reached on Mon. - Thurs. 6:30-5:00; Every Fri. off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. H./

Examiner, Art Unit 1797

/Jan M. Ludlow/

Primary Examiner, Art Unit 1797